UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VTT TECHNICAL RESEARCH CENTRE OF FINLAND LTD., Plaintiff, v. DIAZYME LABORATORIES, INC., Defendant.	CASE NO.: _____ **DEMAND FOR JURY TRIAL**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff VTT Technical Research Centre of Finland Ltd. files this Complaint and demand for a jury trial seeking relief for patent infringement by Defendant Diazyme Laboratories, Inc. Plaintiff states and alleges the following:

THE PARTIES

1. Plaintiff VTT Technical Research Centre of Finland Ltd. ("VTT") is a globally recognized research organization engaged in scientific and technological innovation. VTT is a limited company organized and existing under the laws of Finland, with its headquarters in Espoo, Finland. VTT's principal place of business is located at Tekniikantie 21, Espoo, PL1000, 02044 VTT, Finland.

2. Established in 1942, VTT operates under the mandate of Finland's Ministry of Employment and the Economy, with a mission of advancing science and technology for the benefit of industry, society, and innovation worldwide. Over the past eight decades, VTT has conducted groundbreaking research, translating scientific discoveries into real-world applications that address significant industry challenges.

3. VTT's research encompasses both fundamental and applied research across numerous technical fields, including biotechnology, advanced materials, artificial intelligence, semiconductor technology, imaging, information and communication technology, sustainable energy solutions, and automation. This research, including the innovations that led to the patent-in-suit, is supported by substantial investments from both public and private sources. VTT conducts approximately $190 million in research annually, funded by sources including the Finnish government, the European Union, and private industry partners who recognize VTT's role as a global leader in technology development.

4. VTT's employs a world-class team of more than 1,500 scientists, researchers, and engineers, whose expertise benefits entities worldwide, including governments, businesses, academic institutions, and consumers. Annually, over 1,100 companies collaborate with VTT to enhance their products and services through research and development. To maximize the impact of its research, VTT actively patents and commercializes its inventions, allowing breakthrough technologies to reach the market and funding investment into further innovation.

5. VTT holds more than 1,400 granted patents, with over 500 additional patent applications pending worldwide. Among these patented innovations are immunoassays, which play a critical role in detecting and diagnosing medical conditions, ensuring food safety, and monitoring environmental factors. One such innovation is a noncompetitive immunoassay designed to detect and quantify small analytes, which was granted protection by the United States Patent and Trademark Office as U.S. Patent No. 7,749,712 ("the '712 patent"). VTT's pioneering research in this area has contributed substantially to advancements in medical diagnostics, enhancing both the efficiency and sensitivity of diagnostic assays.

6. On information and belief, Defendant Diazyme Laboratories, Inc. ("Diazyme") is incorporated under the laws of the State of Delaware with a place of business at 12889 Gregg Ct., Poway, California, 92064. Diazyme designs, develops, manufactures, markets, offers for sale, and sells diagnostic tests. Among its products, Diazyme offers diagnostic kits marketed under the trade name "EZ Vitamin D Assay," designed to measure vitamin D levels in blood samples. On information and belief, Diazyme's EZ Vitamin D assay products infringe one or more claims of the '712 patent.

7. On information and belief, Diazyme has long been aware of VTT's pioneering contributions to immunoassay technology and have directly benefited from advancements in the field developed by VTT. Diazyme has incorporated core aspects of VTT's patented innovations into their immunoassay products, without authorization. Despite knowing of the technical significance and patent protection surrounding VTT's inventions, Diazyme has continued to commercialize and profit from infringing products, including the Accused Instrumentalities (defined below), rather than seeking a license from VTT. Its continued exploitation of VTT's immunoassay advancements constitutes direct, indirect, and willful infringement of the '712 patent, as detailed in this Complaint.

8. VTT brings this action to protect its intellectual property rights and to secure fair compensation for Diazyme's unauthorized use of its patented immunoassay technology.

THE ASSERTED PATENT

9. On July 6, 2010, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '712 patent, entitled "Noncompetitive Immunoassay for Small Analytes." The '712 patent originates from Finnish Application No. 20022048, filed on November 18, 2002. VTT is the owner of the entire right, title, and interest in and to the '712 patent, including the

right to sue for and collect damages for past and ongoing infringement. A true and correct copy of the '712 patent is attached to this Complaint as Exhibit A.

10. Claim 1 of the '712 patent is directed to a novel non-competitive immunoassay for detecting small analytes and reads as follows:

> A non-competitive immunoassay for detecting a small analyte, said assay comprising:
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> reacting a sample containing said analyte with a reagent pair comprising a first binding partner that binds to said analyte, and a second binding partner that binds to the complex of said analyte and said first binding partner,
>
> wherein said second binding partner is obtained from a non-immunized source which is a naive display recombinant binding partner library by selecting a binding partner that binds to said complex of the analyte and first binding partner, and
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> determining the binding of the second binding partner, thus indicating the presence of the analyte in the sample, wherein the analyte has a molecular weight of less than 5000.

11. Before the inventions disclosed in the '712 patent, noncompetitive "sandwich" immunoassays were generally effective only for detecting analytes with relatively high molecular weights. Small analytes, typically with molecular weights under 5000 Daltons, presented significant challenges for such assays due to their limited surface area, which hindered the ability to identify antibodies capable of simultaneously binding to the analyte—a requirement for effective sandwich immunoassays. Existing methods attempted to overcome this limitation by generating antibodies through the immunization of animals, a process that was labor-intensive, time-consuming, and often yielded inconsistent results.

12. The inventors of the '712 patent addressed these longstanding challenges by developing a novel approach that enables non-competitive immunoassays for small analytes without relying on antibodies derived from immunized animals. Specifically, the inventors

discovered that selecting binding partners from a naïve display recombinant antibody library could produce second binding partners capable of specifically recognizing the complex formed between a small analyte and a first binding partner. This strategy allowed for the creation of sensitive and specific assays for small molecules, circumventing the need for animal immunization and expanding the applicability of sandwich immunoassays to a broader range of analytes.

13. By overcoming the technical barriers associated with detecting small analytes, the '712 patent represents a significant advancement in immunoassay technology. It provides a practical and efficient method for the sensitive and specific detection of low-molecular-weight compounds, facilitating faster assay development and broader diagnostic applications. This innovation has enabled the widespread adoption of non-competitive immunoassays for small analytes, which was previously unattainable with conventional techniques.

14. To the extent applicable, VTT has complied with 35 U.S.C. § 287 with respect to the '712 patent.

JURISDICTION AND VENUE

15. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 101, *et seq*. This Court has original subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over Diazyme because it is incorporated in the State of Delaware and therefore resides in this State. Moreover, this Court has personal jurisdiction over Diazyme consistent with the Due Process Clause of the United States Constitution and the Delaware Long-Arm Statute because the claims asserted herein arise out of or are related to Diazyme's business activities in this State, including, on information and belief,

at least a portion of the infringing acts alleged in this Complaint. Further, on information and belief, Diazyme regularly transacts business, engages in persistent conduct, and derives substantial revenue in Delaware from goods and services, including those incorporating the Accused Instrumentalities. 10 Del. C. § 3104.

17. Venue is proper in this District pursuant to at least 28 U.S.C. § 1400 because Diazyme is incorporated in the State of Delaware, and therefore resides in the District of Delaware.

BACKGROUND

18. Diazyme has long been aware of VTT's innovations in immunoassay technology, including the patented inventions of the '712 patent. For example, Diazyme became aware of VTT's '712 patent at least by 2019, when the United States Patent and Trademark Office ("USPTO") directly cited it against Diazyme's own patent application during prosecution. Diazyme's website identifies its EZ Vitamin D Assay as being described in a patent application that ultimately issued as U.S. Patent No. 11,435,367 ("the '367 patent"), a true and correct copy of which is attached hereto as Exhibit B. During prosecution of that patent application, the USPTO issued an Office Action dated August 26, 2019, rejecting Diazyme's then-pending claims as obvious in view of the patent application corresponding to VTT's '712 patent. The examiner specifically analyzed the disclosure of the '712 patent, providing a detailed explanation at pages 17–18 of the Office Action regarding its teachings and their relevance to Diazyme's purported invention (citations omitted, emphasis in original):

> [**'712 patent**], throughout the publication and, for example, in paragraph [0007], teach[es] that a non-competitive immunoassay protocol for small analytes, which circumvents the immunisation of animals with the immune complex, which has been so far the most challenging task when a secondary anti-immune complex (anti-IC) antibody, which binds primary anti-analyte antibody that is combined with the analyte but which does not

> bind the primary antibody or the analyte alone have been developed; this also facilitates a homogenous immunoassay, which further improves the speed, sensitivity and simplicity of the assay. In paragraph [0008], [**'712 patent**] teach[es] that:
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> The difficulties associated with raising anti-IC antibodies for use in immunoassays for small analytes can now be avoided by providing the necessary anti-IC antibodies from a display recombinant binding partner library instead of from immunised animals. A phage display antibody library may be constructed, which contains a vast number of clones, from which those coding the desired binding partners, such as antibody fragments, can be enriched and selected through sequential panning. This protocol opens new possibilities for developing rapid, reliable and simple immunoassays for small analytes in a cost-effective and feasible way.
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> * * *
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> One of ordinary skill in the art would have been made and used a homogenious [sic] particle-enhanced immunoassay in non-competitive (direct) format, taught by **Hillyard** *et al.,* for determining the concentration of 25-hydroxy-vitamin D in the method, taught by **Sackrison** *et al.,* because it would be desirable to employ a homogenous immunoassay, which further improves the speed, sensitivity and simplicity of the assay, as taught by [**the '712 patent**].
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> * * *
>
> Moreover, as taught by [**the '712 patent**], the difficulties associated with raising anti-IC antibodies for use in immunoassays for small analytes can be avoided by providing the necessary anti-IC antibodies from a display recombinant binding partner library instead of from immunised animals.

19. The USPTO's direct citation of the '712 patent informed Diazyme of its existence, scope, and relevance to the very immunoassay technologies Diazyme now uses in its infringing products.

20. The USPTO repeatedly cited the patent application corresponding to VTT's '712 patent in support of multiple obviousness rejections issued against Diazyme's patent application.

The examiner relied on the teachings of the ’712 patent to demonstrate that key aspects of Diazyme’s claimed invention were already disclosed or rendered obvious by prior art—including the innovative immunoassay techniques pioneered by VTT.

21. In responding to these rejections, Diazyme never attempted to distinguish its assay on the ground that it employed a fundamentally different type of binding partner than that disclosed in the ’712 patent. Despite having every opportunity to do so, Diazyme made no assertion that its assay design materially differed from the approach claimed in the ’712 patent—particularly with respect to the use of a second binding partner selected from a naïve display recombinant library to detect a small analyte.

22. Diazyme’s analysis of the ’712 patent during prosecution confirms not only that Diazyme had actual knowledge of the patent, but also that it understood the patent’s core technical teachings and their relevance to Diazyme’s own EZ Vitamin D Assay—one of the products accused of infringement in this Complaint. Diazyme’s failure to distinguish the ’712 patent underscores its recognition that the assay it developed falls squarely within the scope of VTT’s patented invention.

23. After discovering Diazyme’s infringing EZ Vitamin D Assay in the marketplace, VTT provided formal written notice of infringement on July 23, 2024. In that notice, VTT expressly identified the ’712 patent and informed Diazyme that its EZ Vitamin D Assay infringes one or more of the patent’s claims. In this letter, addressed to Diazyme’s Co-Founder and Managing Director, Dr. Chong Yuan, VTT enclosed a copy of the ’712 patent along with a detailed claim chart. The chart mapped each element of a representative claim—particularly claim 1—to Diazyme’s EZ Vitamin D Assay. The claim chart highlighted, among other things, that the application underlying Diazyme’s ’367 patent describes an assay that incorporates a

reagent pair comprising: (i) a first monoclonal anti-Vitamin D antibody (a first binding partner) that binds to Vitamin D, and (ii) a second monoclonal antibody made in vitro (a second binding partner) that binds the complex formed by the analyte (Vitamin D) and the first binding partner. This configuration squarely incorporates the core innovation disclosed and claimed in the '712 patent. VTT invited Diazyme to engage in licensing discussions to amicably resolve the matter.

24. In a letter dated August 29, 2024, Diazyme indicated that Affimedix, Inc., supplies its second binding partner, and argued that the EZ Vitamin D Assay does not infringe the '712 patent because that second binding partner was derived from a synthetic antibody library. In related correspondence, Affimedix confirmed that the process for preparing the second binding partner is described in Example 3 of U.S. Patent No. 11,073,524 ("the '524 patent"), a true and correct copy of which is attached hereto as Exhibit C.

25. VTT responded in a letter dated September 4, 2024, explaining that the claims of the '712 patent encompass binding partners from both synthetic and naturally derived antibody diversity, provided they were not generated using immunized animals, *i.e.* that the antibody library be "naive." VTT supported this position by citing the '712 patent specification (col. 5, lines 1-3) and its prosecution history—specifically Remarks and Amendments dated August 28, 2008—to demonstrate that the term "naïve," as used in the '712 patent, encompasses synthetic libraries. That document emphasized the novelty of the invention as eliminating the need for immunization of animals: "[T]he difficulties associated with raising anti-IC antibodies can be avoided by providing the necessary anti-IC antibodies from a display recombinant binding partner library, instead of from immunized animals. Thus, the point of such is that the desired second binding partner of the claims is obtained from a nonimmunized source. In other words,

the desired second binding partner is obtained from a naive binding partner library[.]"[1] Thus, "naïve" merely denotes a non-immunized source and does not distinguish between synthetic and natural antibody diversity.

26. On November 4, 2024, VTT provided Diazyme with authoritative scientific literature confirming that "naïve" libraries may include synthetic antibody libraries. Representative examples included:

- C.J. Bond et al., "Contributions of CDR3 to VhH Domain Stability and the Design of Monobody Scaffolds for Naïve Antibody Libraries," 332 J. MOLECULAR BIOLOGY 643, 644 (2003) (referring to "a naïve, synthetic antibody library.")
- S. Cesaro-Tadic et al., "Turnover-based in vitro selection and evolution of biocatalysts from a fully synthetic antibody library," 21 NATURE BIOTECHNOLOGY 679, 679 (June 2003) (describing a "naive antibody library . . . made from fully synthetic, antibody-encoding genes" and a "naïve, fully synthetic library.")

27. Diazyme never responded to VTT's November 4, 2024 letter. On January 30, 2025, VTT followed up in writing, reiterating its concerns and renewing its invitation to engage in good-faith discussions. Diazyme again failed to respond. Instead, it continued to manufacture, market, and sell its EZ Vitamin D Assay, despite being on actual notice of the '712 patent and VTT's infringement allegations. Diazyme's continued exploitation of VTT's patented technology occurred without authorization and without any effort to compensate VTT.

[1] VTT similarly stated, in pages 6-7 of Remarks and Amendments dated May 14, 2009, that "the use of a naive recombinant binding partner library provides a complete solution to the problems associated with immunizing with an immune complex" and an "inventive concept" of the invention was obtaining "appropriate second binding partners that recognize a complex of analyte and first binding partner . . . from a non-immunized source, whereby no immunization with an immune complex is required."

28. Diazyme has not obtained, and does not have, either an express or implied license to the ’712 patent. Its ongoing commercialization of the infringing EZ Vitamin D Assay constitutes unauthorized and infringing use of VTT’s patented technology.

29. On information and belief, Diazyme has taken no meaningful steps to design around or otherwise avoid infringement of the ’712 patent, despite its knowledge. Instead, Diazyme continues to knowingly and deliberately profit from the patented technology while disregarding VTT’s intellectual property rights. Its refusal to engage in good-faith discussions, and continued manufacture and sale of infringing products underscore the willful nature of Diazyme’s infringement.

COUNT I

(Infringement of the ’712 Patent)

30. VTT restates and realleges all the foregoing paragraphs as if fully stated herein.

31. On information and belief, Diazyme has directly infringed and continues to directly infringe one or more claims of the ’712 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, because it has made, used, sold, offered for sale, and/or imported and is currently making, using, selling, offering for sale, and/or importing the Accused Instrumentalities. The Accused Instrumentalities include the EZ Vitamin D Assay, as well as any other assays for detecting analytes having a molecular weight of less than 5000 using a reagent pair comprising: (a) a first binding partner that binds to the analyte, and (b) a second binding partner obtained from a naive display recombinant binding partner library that specifically binds to the complex formed between the analyte and first binding partner.

32. On information and belief, Diazyme's Accused Instrumentalities satisfy all elements of at least claim 1 of the '712 patent, which is set forth below and addressed in the paragraphs that follow:

> A non-competitive immunoassay for detecting a small analyte, said assay comprising:
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> reacting a sample containing said analyte with a reagent pair comprising a first binding partner that binds to said analyte, and a second binding partner that binds to the complex of said analyte and said first binding partner, wherein said second binding partner is obtained from a non-immunized source which is a naive display recombinant binding partner library by selecting a binding partner that binds to said complex of the analyte and first binding partner, and determining the binding of the second binding partner, thus indicating the presence of the analyte in the sample, wherein the analyte has a molecular weight of less than 5000.

33. On information and belief, Diazyme's Accused Instrumentalities include a non-competitive immunoassay for detecting a small analyte.

34. For example, Diazyme's EZ Vitamin D Assay detects 25-hydroxyvitamin D ("25-OH-D"), a form of Vitamin D with a molecular weight of approximately 400 Da—well under the 5000 Da threshold recited in the claim. This is a "small analyte."

35. Diazyme's website and marketing materials describe the EZ Vitamin D Assay as a "510(k) Cleared" two-reagent immunoassay for the quantitative measurement of Vitamin D2 and D3 in human serum and plasma, within a range of "7.6 – 147.8 ng/mL." The assay requires only 3 µL of serum or plasma per test and is described as having "excellent assay precision." An exemplary Sales Sheet is available on Diazyme's website and attached as Exhibit D.

36. According to the FDA's 510(k) Decision Summary for the EZ Vitamin D Assay, attached as Exhibit H, the intended use of the product is "the quantitative determination of 25-

hydroxyvitamin D (25-OH-D) in human serum and plasma." Ex. H at 2. This confirms that the assay detects a small analyte in a biological sample.

37. On information and belief, Diazyme's Accused Instrumentalities react a sample containing a small analyte with a reagent pair comprising a first binding partner that binds to the analyte.

38. For example, the EZ Vitamin D Assay uses a first monoclonal antibody that serves as a "capture antibody" for Vitamin D in the sample. Diazyme's scientific article attached as Exhibit E, *First two-reagent vitamin D assay for general clinical chemistry* (co-authored by Dr. Chong Yuan), describes this first monoclonal antibody as binding specifically to 25-OH Vitamin D in the sample, forming a complex between the analyte and the antibody.

39. Diazyme also maintains a product page on its website for its EZ Vitamin D Assay, attached as Exhibit F. On this product page, Diazyme references the published patent application that ultimately issued as the '367 patent. This application, which is attached as Exhibit G, explains that the first antibody "specifically binds to vitamin D." Ex. G at ¶ 76. The application also notes that the sample is reacted with the reagent pair to determine the amount of Vitamin D present. *Id.* at ¶ 49.

40. On information and belief, Diazyme's Accused Instrumentalities include a second binding partner that binds to the complex formed by the analyte and the first binding partner.

41. For example, the same application for Diazyme's '367 patent describes a second monoclonal antibody that "specifically binds to the complex formed between the first antibody and the vitamin D moiety." Ex. G at ¶ 76.

42. Similarly, the scientific article by Dr. Yuan, which Diazyme also references on its product page, explains that the second antibody in the EZ Vitamin D Assay "serves as a

detection antibody that recognizes the capture antibody when it is bound to a vitamin D molecule." Ex. E at 2. This demonstrates that the second binding partner binds not just to Vitamin D, but specifically to the complex formed between the analyte and the first monoclonal antibody.

43. A figure published in the same article illustrates this interaction by showing that the second antibody binds to the analyte-antibody complex, completing the sandwich configuration required by the claim:

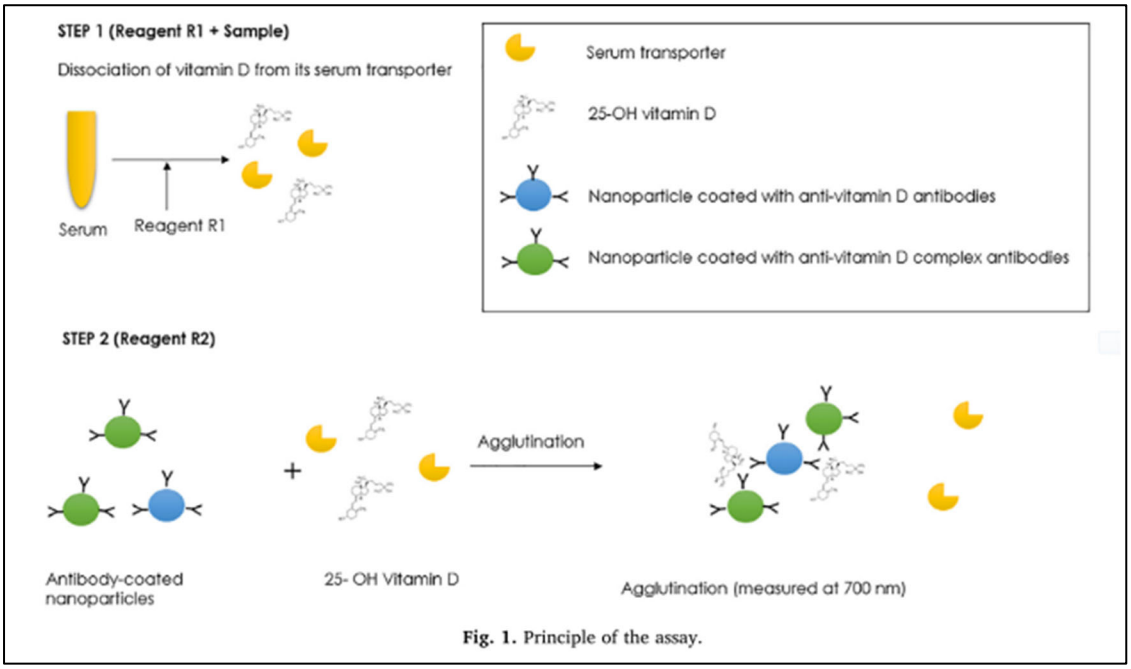

Fig. 1. Principle of the assay.

Ex. E at 2.

44. On information and belief, Diazyme's Accused Instrumentalities use a second binding partner that is obtained from a non-immunized source—specifically, a naïve display recombinant binding partner library selected for its ability to bind the analyte-antibody complex.

45. For example, Diazyme has confirmed that its second binding partner is supplied by Affimedix, Inc. In correspondence with VTT, Affimedix stated that the second monoclonal antibody is developed as described in Example 3 of the '524 patent."

46. Example 3 of the ’524 patent discloses methods for preparing antibodies from antibody combinatorial libraries that were not derived from immunized animals or exposed to antigens. These methods are used to generate monoclonal antibodies that bind to the complex formed between 25-OH Vitamin D and a monoclonal antibody. Ex. C at 23:17-25:46.

47. In Diazyme’s scientific article, Dr. Yuan confirms that “the detection antibody was developed in vitro using antibody combinatorial libraries,” and not derived through animal immunization, showing that the second binding partner was selected from a “naïve” display library. Ex. E at 2.

48. On information and belief, the process used by Affimedix to generate the second antibody did not involve exposure of the library to an antigen or immunization of any host, and instead relies on screening a recombinant antibody library for binding to the immune complex—precisely as required by claim 1.

49. On information and belief, Diazyme’s Accused Instrumentalities determine the presence of the analyte in the sample by measuring the binding of the second binding partner to the complex of the analyte and the first binding partner.

50. For example, Diazyme’s scientific article explains that detection of the analyte is accomplished by observing whether the second antibody binds to the complex formed by Vitamin D and the first antibody. The degree of this binding is then used to quantify the amount of 25-OH Vitamin D in the patient sample.

51. The FDA’s 510(k) Decision Summary similarly confirms that the intended use of the EZ Vitamin D Assay is to quantitatively determine the concentration of 25-OH Vitamin D, which occurs by detecting the binding event between the second antibody and the analyte-antibody complex. Ex. H at 2-3.

52. On information and belief, the analyte detected by Diazyme's Accused Instrumentalities has a molecular weight of less than 5000.

53. For example, 25-hydroxyvitamin D, the target analyte of the EZ Vitamin D Assay, has a molecular weight of approximately 400 Da.

54. Based on the foregoing allegations and supporting evidence, Diazyme's Accused Instrumentalities satisfy each and every element of at least claim 1 of the '712 patent. Accordingly, Diazyme has directly infringed and continues to directly infringe the '712 patent in violation of 35 U.S.C. § 271(a).

55. Diazyme's infringement of the '712 patent has also been indirect.

56. On information and belief, Diazyme has indirectly infringed and continues to indirectly infringe one or more claims of the '712 patent under 35 U.S.C. § 271(b), because it has induced and continues to induce third parties (including its customers, distributors, and end users) to use the Accused Instrumentalities, which lack any use or function other than to perform the assay covered by the '712 patent. Such use by third parties constitutes direct infringement of one or more claims of the '712 patent.

57. For example, on information and belief, Diazyme has supplied and continues to supply such induced third parties with the Accused Instrumentalities along with instructions, technical guidance, marketing materials, product brochures, datasheets, and other related content that instructed/instruct them how to use the Accused Instrumentalities, with knowledge that usage in accordance with their instructions directly infringed/infringe one or more claims of the '712 patent, or with willful blindness to that fact.[2] On information and belief, Diazyme will

[2] *E.g.*, Exs. B, D, E, F, G, and H. On information and belief, Diazyme provides additional "Technical Documentation" to purchasers of the EZ Vitamin D Assay that provide additional instructions and guidance on performance of the EZ Vitamin D Assay through its website, but access of these materials requires a registered account with Diazyme.

continue to encourage, aid, or otherwise cause these third parties to, for example, use their Accused Instrumentalities in ways that directly infringe the ’712 patent, and Diazyme has and will continue to encourage these acts with the specific intent to infringe the ’712 patent. Alternatively, Diazyme has acted with willful blindness to these facts. On information and belief, Diazyme knows that there is a high probability that the use of the Accused Instrumentalities constitutes direct infringement of the ’712 patent but took deliberate actions to avoid learning of these facts.

58. On information and belief, Diazyme has been aware of the inventions described and claimed in the ’712 patent since shortly after its issuance. At a minimum, Diazyme had actual knowledge of the ’712 patent no later than August 26, 2019, when the USPTO issued an Office Action rejecting Diazyme’s then-pending claims—later issued as the ’367 patent—as obvious in light of a published patent application corresponding to the ’712 patent. In that Office Action, the examiner specifically cited and analyzed the disclosure of the ’712 patent, placing Diazyme on clear and unequivocal notice of its existence, scope, and direct relevance to the immunoassay technology disclosed in Diazyme’s own application—an application that Diazyme has acknowledged describes the EZ Vitamin D Assay accused of infringement. This citation confirms that Diazyme was not only aware of the ’712 patent, but also understood its material significance to the very products it now manufactures, markets, and sells.

59. Diazyme’s knowledge of the ’712 patent goes well beyond mere awareness—its own communications confirm a clear recognition of the patent’s relevance to its products. On July 23, 2024, VTT provided Diazyme with formal written notice of infringement, enclosing a detailed claim chart mapping each element of the ’712 patent to Diazyme’s EZ Vitamin D Assay. Rather than dispute its knowledge of the patent, Diazyme’s response acknowledged it and

engaged in a discussion regarding infringement. Yet Diazyme failed to offer any meaningful technical explanation distinguishing its assay from the patented invention. Its only assertion—that its second binding partner was derived from a synthetic antibody library—was legally and technically irrelevant, as the '712 patent explicitly encompasses such antibodies so long as they are obtained from non-immunized sources. Diazyme's inability to articulate a credible non-infringement position, when viewed alongside its prior knowledge of the '712 patent through its independent analysis of the 2019 USPTO Office Action and VTT's formal notice, underscores the willful and deliberate nature of its continued infringement.

60. On information and belief, Diazyme has known—or has remained willfully blind to the fact—that the use of the Accused Instrumentalities by third parties, including customers, distributors, and end users, constitutes acts of direct infringement of the '712 patent. Diazyme has long been on notice that the use of its EZ Vitamin D Assay and related products directly infringes the claims of the '712 patent. Despite this knowledge, Diazyme has continued to market, sell, and actively promote the Accused Instrumentalities, encouraging their use by third parties in ways that it knows, or should know, result in direct infringement. Rather than investigate or take steps to mitigate its infringement, Diazyme has deliberately disregarded VTT's patent rights—failing to provide any meaningful response, legal justification, or technical distinction. At a minimum, Diazyme's refusal to engage in good-faith discussions or identify any reasonable non-infringement position, combined with its continued inducement of infringing use, demonstrates willful blindness and a calculated effort to evade liability.

61. On information and belief, Diazyme has also indirectly infringed and continues to indirectly infringe one or more claims of the '712 patent under 35 U.S.C. § 271(c), because it has

contributed and continues to contribute to the direct infringement of third parties (including its customers, distributors, and end users) who assemble and use the Accused Instrumentalities.

62. For example, Diazyme has sold, offered for sale, and/or imported into the United States components of the Accused Instrumentalities with full knowledge of the ’712 patent, and continues to do so. These components include reagent elements comprising (1) a first monoclonal antibody that binds to Vitamin D and (2) a second monoclonal antibody—generated using a naïve display recombinant library—that binds to the complex formed by the analyte and the first antibody. Alternatively and/or additionally, Diazyme has sold, offered for sale, and/or imported into the United States, the Accused Instrumentalities—including the EZ Vitamin D Assay itself—which constitute a material apparatus for use in practicing the patented processes claimed in the ’712 patent, and continues to do so. Diazyme provides these products to third parties with knowledge of the ’712 patent and with the intention that they be used to perform the patented method(s). These third parties have assembled and used the Accused Instrumentalities in accordance with Diazyme’s instructions, technical documentation, marketing materials, product brochures, datasheets, and related guidance, all of which explain and encourage use of the assay in a manner that infringes the ’712 patent. The Accused Instrumentalities and their components lack any meaningful use or function other than to infringe the ’712 patent and are not staple articles or commodities of commerce suitable for substantial non-infringing use. The Accused Instrumentalities constitute a material part of the inventions claimed in the ’712 patent and were specifically designed and marketed by Diazyme to be used in a manner that infringes the ’712 patent. Diazyme knew and intended that the Accused Instrumentalities be especially made or adapted for use in infringing the ’712 patent. Such assembly and/or use by third parties

constitutes direct infringement of one or more claims of the ’712 patent, and Diazyme’s knowing provision of these materials constitutes contributory infringement under 35 U.S.C. § 271(c).

63. On information and belief, Diazyme’s infringement of the ’712 patent has been and continues to be willful and merits enhanced damages.

64. For example, Diazyme has known of the ’712 patent and its infringement of the ’712 patent as described herein.

65. On information and belief, since knowing of the ’712 patent and its infringement thereof, Diazyme has not taken any affirmative steps to avoid infringing the ’712 patent.

66. On information and belief, Diazyme has made no attempt to design around the claims of the ’712 patent.

67. On information and belief, Diazyme has no reasonable basis for believing that the claims of the ’712 patent are either invalid or not infringed by the Accused Instrumentalities.

68. VTT has been damaged as the result of Diazyme’s willful infringement.

69. On information and belief, Diazyme will continue to infringe one or more claims of the ’712 patent unless and until they are enjoined by this Court.

70. On information and belief, Diazyme has caused and will continue to cause VTT irreparable injury and damage by infringing the ’712 patent. VTT will suffer further irreparable injury and damage, for which it has no adequate remedy at law, unless and until Diazyme is enjoined from infringing the claims of the ’712 patent.

JURY DEMAND

71. VTT requests a jury trial as to all issues that are triable by a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, VTT respectfully requests that this Court:

A. Enter judgment that Diazyme has infringed one or more of the claims of the ’712 patent;

B. Enter an order permanently enjoining Diazyme and its officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, from infringing the ’712 patent;

C. Award VTT all appropriate damages for the infringement of the ’712 patent, including pre-judgment and post-judgment interest, costs, and all other relief permitted under 35 U.S.C. § 284;

D. Award VTT an accounting for acts of infringement not presented at trial, including an award of additional damages for such acts of infringement;

E. Enter judgment that Diazyme’s infringement of the ’712 patent has been deliberate and willful;

F. Treble the damages awarded to VTT under 35 U.S.C. § 284 by reason of the Diazyme’s willful infringement of one or more claims of the ’712 patent;

G. Declare this case to be “exceptional” under 35 U.S.C. § 285 and award VTT its attorneys’ fees, expenses, and costs incurred in this action; and

H. Award VTT such other and further relief at law or in equity as the Court deems just and proper.

Dated: May 29, 2025

Respectfully submitted,

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